Attorney's Docket No.: 701334-3001
Application No.: 10/038,730

REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application are respectfully requested.

Status

Claims 32-41, 43, 44, 46, 53-57, and 59 are pending. *See Office Action Mailed October 18, 2005, Office Action Summary, Item 4.* Claims 32-41, 43, 44, 46, 53-57, and 59 stand rejected. *Id. at Item 6.*

Summary of Claim Amendments

By the foregoing claim amendments, Applicants have amended independent Claim 32 to specify that the vaso-occlusive precursor composition comprises a polymer-forming, or dissolved polymeric, biodegradable material and a biologically active component, wherein the polymer-forming, or dissolved polymeric, biodegradable material is present in an amount of about 5 to 50% by weight based on the overall content of the composition. Support for this amendment may be found throughout the Specification, and at least at Page 5, Lines 20-22; Page 12, Lines 13-15; and original Claim 1. Accordingly, no new matter has been added.

Rejections Under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 32-41, 43, 44, 46, 53-57, and 59 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly lacking sufficient written description. *See Office Action Mailed October 18, 2005, Pages 2-3.* According to the Examiner, "[t]he claims do not specify what is to be taken into account when calculating the percent weight of the vaso-occlusive precursor." *Id. at Page 3.* These rejections are respectfully traversed.

Not to acquiesce in the Examiner's rejections, but solely to facilitate prosecution, Applicants have amended independent Claim 32 to specify that the vaso-occlusive precursor composition comprises a polymer-forming, or dissolved polymeric, biodegradable material and a biologically active component, wherein the polymer-forming, or dissolved polymeric, biodegradable material is present in an amount of about 5 to 50% by weight based on the overall content of the composition. This amendment simply makes explicit what was taught in the Specification at Page 5, Lines 20-22; Page 12, Lines 13-15; and original Claim 1.

In light of the foregoing, Applicants respectfully request that the 35 U.S.C. § 112, First Paragraph, written description rejection of Claims 32-41, 43, 44, 46, 53-57, and 59 be withdrawn.

Rejections Under 35 U.S.C. § 102(e) Over Evans

Claims 32, 33, 38, 39, 53-55, and 59 were rejected under 35 U.S.C. § 102(e) as purportedly anticipated by U.S. Patent No. 5,702,361 to Evans *et al.* ("Evans"). *See Office Action Mailed October 18, 2005, Pages 4-5.* These rejections are respectfully traversed.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Moreover, inherent anticipation requires that the missing descriptive material is *necessarily present*, not merely probably or possibly present, in the cited prior art. *See In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

Applicants respectfully assert that Evans fails to disclose all elements of Claims 32, 33, 38, 39, 53-55, and 59. Claims 32, 33, 38, 39, 53-55, and 59 require a system for forming a biologically active anatomical occlusion in an anatomical cavity, wherein that system comprises a vaso-occlusive precursor composition comprising a biologically active component, and a mechanical device. Evans fails to contain at least the biologically active

component element of Claims 32, 33, 38, 39, 53-55, and 59. Applicants' Specification indicates that the biologically active component is "preferably a medicine or angiogenic material" (*see Specification, Page 6, Lines 17-18*) and sets forth in detail non-limiting examples of such bioactive materials. *See Specification, Page 7, Line 23 to Page 11, Line 3.* The non-particulate agents of Evans are not Applicants' biologically active components.

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(e) rejections of Claims 32, 33, 38, 39, 53-55, and 59 over Evans.

Rejections Under 35 U.S.C. § 103(a) Over Evans In View Of Slepian

Claims 32 and 34-36 were rejected under 35 U.S.C. § 103(a) as purportedly obvious over Evans in view of U.S. Patent No. 5,634,946 to Slepian ("Slepian"). *See Office Action Mailed October 18, 2005, Pages 6-8.* These rejections are respectfully traversed.

With regarding to the alleged obviousness, to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See MPEP § 2142.*

When applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole; (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986).

Moreover, mere identification of each claimed element in the prior art is NOT sufficient to negate patentability. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Instead, there "must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the filed of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 536 (Fed. Cir. 1998). Otherwise, sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. *Rouffet*, 149 F.3d at 1357.

Applicants respectfully submit that *prima facie* case of obviousness based on Evans in view of Slepian has not been made out. As indicated above, Evans fails to disclose or suggest at least the biologically active element of Claims 32 and 34-36. Slepian's particular polymers do not cure this fundamental deficiency in Evans.

Moreover, Evans and Slepian not only fail to disclose or suggest all elements of Claims 32 and 34-36, but these two publications also fail to provide the necessary reasonable expectation of success. Evans makes clear that it is the *combination* of the non-particulate agent and the polymer composition that sets the invention apart from "deficiencies associated with each of these embolizing procedures when used separately." *See, e.g., Evans at Column 3, Lines 39-44.* One of skill in the art prior to Applicants' invention would not have expected success if he removed the non-particulate element of Evans' invention.

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 32 and 34-36 over Evans in view of Slepian.

Rejections Under 35 U.S.C. § 103(a) Over Evans In View Of Murayama

Claims 32, 40, 41, 43, 44, and 46 were rejected under 35 U.S.C. § 103(a) as purportedly obvious over Evans in view of U.S. Patent No. 5,891,192 to Murayama *et al.* ("Murayama"). *See Office Action Mailed October 18, 2005, Pages 8-9.* These rejections are respectfully traversed.

As explained fully above, Claims 32, 40, 41, 43, 44, and 46 all require a system for forming a biologically active anatomical occlusion in an anatomical cavity, wherein that system comprises a vaso-occlusive precursor composition comprising a biologically active component, and a mechanical device. Evans fails to contain at least the biologically active component element of these claims. The proteins of Murayama do not cure this fundamental deficiency.

Moreover, as with Evans in combination with Slepian, Evans in combination with Murayama fail to provide the necessary reasonable expectation of success. Both Evans and Murayama require the use of non-particulate agents, such as coils and stents. If one of skill in the art prior to Applicants' invention were to remove that aspect from Evans and/or Murayama, he would not have expected to succeed in arriving at a biologically active anatomical occlusion system.

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 32, 40, 41, 43, 44, and 46 over Evans in view of Murayama.

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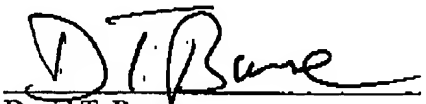
Application No.: 10/038,730

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone so that prosecution of the application may be expedited.

Respectfully submitted,
BINGHAM MCCUTCHEN, LLP

Date: 1/24/06 By: 

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